REMARKS

In the Office Action dated June 16, 2004, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following separate and distinct inventions:

I. Claims 1-4, and 6-10, drawn to a protein, classified in class 530, subclass 300.

II. Claims 123, 31 drawn to a nucleic acid , classified in class 536, subclass 23.72.

III. Claims 23, 28, and 29, drawn to a method for recombinant production of a protein, classified in class 435, subclass 69.1.

IV. Claim 44, drawn to a method of vaccinating, classified in class 424, subclass 187.1.

V. Claim 49, drawn to a method of distinguishing one coronavirus from another using a protein, classified in class 435, subclass 5.

VI. Claim 49, drawn to a method of distinguishing one coronavirus from another using a primer, classified in class 435, subclass 5.

VII. Claim 49, drawn to a method of distinguishing one coronavirus from another using a nucleic acid, classified in class 435, subclass 5.

VIII. Claim 49, drawn to a method of distinguishing one coronavirus from another using an antibody, classified in class 435, subclass 5.

IX. Claims 51 and 54, drawn to a peptide, classified in class 530, subclass 300.

X. Claims 52 and 54, drawn to a peptide, classified in class 530, subclass 300.

XI. Claim 53, drawn to a DNA sequence, classified in class 536, subclass 23.72.

XII. Claim 55, drawn to an antibody, classified in class 530, subclass 387.1.

XIII. Claim 56, drawn to a method for distinguishing one coronavirus from another using a peptide, classified in class 435, subclass 5.

XIV. Claim 56, drawn to a method for distinguishing one coronavirus from another using a DNA sequence, classified in class 435, subclass5.

XV. Claim 56, drawn to a method for distinguishing one coronavirus from another using an antibody, classified in class 435, subclass 5.

In addition, the Examiner states that:

if Group I is elected, Applicants must further elect

A) one from a)diagnosis, b)treatment, or c)prophylaxis.
In case treatment is elected claim 46 will be examined.
In case prophylaxis is elected, claims 36 and 38 will be examined.

B) a sequence which can be either a SEQ ID# from claim 8 or the SEQ ID# and protein segment from claims 6 and 7.

C) one virus from claims 2-4.

If Group II is elected, Applicants must further elect

A) one from a)diagnosis, b)treatment, or c)prophylaxis.

B) a sequence which can be either a SEQ ID# from claim 8 or the SEQ ID# and protein segment from claims 6 and 7.

C) one virus from claims 2-4.

If Group III is elected, Applicants must elect as required in Group II.

If Group IV is elected, Applicants must elect as required in Group I.

If Group V is elected, Applicants must elect as required in Group I.

If Group VI is elected , Applicants must elect a sequence from Table II (SEQ ID N#s 1-18)

If Group VII is elected, Applicants must elect as required in Group II.

If Group VIII is elected, Applicants must elect a protein from Group I to indicate binding specificity.

If Group IX is elected, Applicants must elect a segment and SEQ ID# that contains the segment and SEQ ID# that represents the segment.

If Group X is elected, Applicants must elect a SEQ ID# ((a) to (i)) or the size that corresponds to ((a) to (i)) in (j).

If Group XI is elected, Applicants must elect one SEQ ID# as required in Group IX or X.

If Group XII is elected, Applicants must elect one SEQ ID# as required in Group IX or X to determine the binding specificity.

If Group XIII is elected, Applicants must elect one SEQ ID# as required in Group IX or X.

If Group XIV is elected, Applicants must elect one SEQ ID# as required in Group IX or X.

If Group XV is elected, Applicants must elect one SEQ ID# as required in Group IX or X.

The Examiner contends that inventions I, II and IX and XII are unrelated. The Examiner states that inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The Examiner alleges that inventions I, II and IX and XII are drawn to different structures (protein, nucleic acid or antibody). The Examiner indicates that each protein, nucleic acid and antibody are different from others of the same kind because they encode different sequences, are proteins with different sequences or are antibodies that bind to different structures.

Furthermore, The Examiner alleges that inventions I, II, and IX-XII (products) and III-VIII and XIII-XV (methods) are related as product and process of use. The Examiner states that inventions can be shown to be distinct if either of both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The Examiner argues that in the instant case the methods can be practiced with the different proteins or nucleic acids as claimed.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, Claims1-4, and 6-10, drawn to a protein comprising a peptide from the S protein of a coronavirus virus strain. As a consequence

of the election of Group I, Applicants further elect for examination A) the protein useful in diagnosis; B) residues 137-151 of SEQ ID No: 22; and C) the WT FIPV DF2 virus. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized.

In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. More specifically, Applicants submit that a principal feature of the present invention is the recognition of the differences between various strains of Feline Infectious Peritonitis Virus (FIPV) and its sister virus, FECV, that are localized within the amino terminal half of the S protein. Therefore, the present invention has provided polypeptide fragments representing discrete portions of the S protein, such as the peptide fragments of Groups I, II, and IX-XII, are useful in developing reagents (e.g., antibodies) for distinguishing or discriminating between serologically similar viruses. Accordingly, Applicants respectfully submit that the peptide fragments of Groups I, II,

and IX-XII are related and linked to each other under a single inventive concept and are not independent.

Furthermore, Applicants respectfully submit that Groups I, II, and IX-XII are merely different aspects of a single invention. The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and recognized divergent subject matter and would require independent searches for each sequence, and for different methods and uses. Thus, the Examiner concludes that restriction for examination purposes is proper.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits

considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute

claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Applicants respectfully submit that the Examiner should at least examine peptides consisting essentially of residues 124-174, 145-150, 138-159, 143-150, 1-748, 1-223, 1-360, 93-223, 94-223, 97-222, 121-180, and 94-748 of SEQ ID NO: 22 together with the elected peptide

consisting essentially of residues 137-151 of SEQ ID NO: 22. Applicants observe that residues 137-151 are within, partially within, or encompass, residues 124-174, 145-150, 138-159, 143-150, 1-748, 1-223, 1-360, 93-223, 94-223, 97-222, 121-180, and 94-748 of SEQ ID NO: 22. Therefore, it would not create an undue burden on the part of the Examiner to conduct a search that would capture both, peptide 137-151 and any other of peptides 124-174, 145-150, 138-159, 143-150, 1-748, 1-223, 1-360, 93-223, 94-223, 97-222, 121-180, and 94-748 of SEQ ID NO: 22.

In addition, Applicants respectfully request the Examiner to jointly examine Group V, Claim 49, drawn to a method of distinguishing one coronavirus from another using a protein. A method of distinguishing one coronavirus from another using a protein that is directly related to the protein of the selected group, as said protein was also selected for diagnosis.

Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

Peter I. Bernstein
Registration No. 43,497

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343

XZ/JM:ab